REMARKS

The only issue outstanding in the Office Action mailed November 20, 2006, are soley the rejections under 35 U.S.C. §112 and the claim objections. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

Claim Objections

The objection to claims 4 and 5 has been rendered moot by cancellation of these claims. The scope of the present application has not been diminished, either literally or for purposes of the doctrine of equivalence, by these amendments.

The examiner is thanked for noting the typographical error in claim 6. Appropriate correction has been made.

Rejections under 35 U.S.C. §112

Claims 9, 10, 14 and 15 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Reconsideration of this rejection is respectfully requested.

The rejection of claim 14 has been rendered moot by cancellation of this claim. Moreover, it is submitted that claim 15 is also allowable, per previous discussions with the examiner in which it was agreed to allow the present application if claim 15 was amended to recite treatment of schizophrenia and psychotic anxiety states.

It is submitted that claims 9 and 10 are fully enabled by the present specification. Although not at issue, it is also submitted that the same enablement applies to prior claim 14. Claims 9 and 10 recite methods for inhibiting serotonin reuptake, and achieving a $5HT_{1A}$ antagonistic effect, by administering compounds according to claim 1. It is apparently argued, at page 3 of the office action, that the breadth of these claims renders them non-enabled. First, at page 12, lines 34 - 36, it is taught that the compounds of formula I inhibit serotonin reuptake and are $5HT_{1A}$ agonists. At page 11of the specification, it is taught that the compounds thus are useful to treat various diseases. Clearly, this discussion, *without more,* is sufficient to establish enablement of claims 9 and 10 for

purposes of §112 of the statute, as it constitutes a scientifically supportable statement of utility which would be plausible to one of ordinary skill in the art.

It is well established that an unsupported suggestion that reactants within a class defined by claims in a typical method of use application would not work, or that such claims embrace inoperative members, insufficient basis alone for rejecting the claims. See *Ex parte Janin*, 209 U.S.P.Q. 761 (POBA 1979). In fact, it is clear that recitations in an Applicants' specification *must* be taken by the PTO as an assertion that all compounds encompassed in the claims are operative in the invention, in the absence of reasons or evidence to the contrary. *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971).

The first paragraph of 35 U.S.C §112 requires only *objective* enablement. Where a specification teaches the manner and process of making and using the invention, the specification *must* be taken as sufficient under §112, unless there is reason to doubt the truth of these statements. See *Marzocchi*, supra. Applicants' specification clearly enables one to make and use the disclosed compounds in the claimed methods.

On the one hand, it is submitted that the Examiner has not provided any such reasons or evidence to doubt the assertion of utility in the specification and, thus, the further steps of the analysis as set forth in *Marzocchi* are not reached. The "unpredictable nature" of some diseases which can be treated by the mechanism of action of the compounds" does not rise to the level of such reasons or evidence. As clearly stated in *Marzocchi*, mere *breadth* of the claims does not, without more, result in non-enablement. As the court stated in *Marzocchi*, supra

> Turning specifically to the objections noted by the Board as indicated above, it appears that these comments indicate nothing more than a concern over the *breadth* of the disputed term. If we are correct, then the relevance of this concern escapes us. It has never been contended that Applicants, when they included the disputed terms in their specification, intended only to indicate a single compound. Accepting, therefore, that the term is a generic one, its recitation must be taken as an assertion by Applicants that all of the 'considerable number of compounds' which are included in the generic term would, as a class, be operative to produce the asserted enhancement of adhesion characteristics. The only

> relevant concern of the patent office under these circumstances should be over the *truth* of any such assertion. The first paragraph of §112 requires nothing more than *objective enablement*. How such a teaching is set forth, either by the use of illustrative examples or by broad term analogy, it is of no importance.

Marzocchi, supra. (Emphasis in original.) Thus, the concern expressed at pages 3 and 4 of the Office Action, apparently that the claimed methods are broad, does not provide the reasons or evidence necessary by *Marzocchi* to pass beyond the necessity merely for objective enablement.

Further, in this regard, it is important to note, as a matter of law, that it is not necessary for Applicants' *method* claims to exclude inoperative embodiments, inasmuch as the claims are interpreted in light of the level of understanding one of ordinary skill in the art and, for methods, are interpreted to be *per se* functional. See *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976) and *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (CCPA 1974). These cases state that, for method claims, inoperative embodiments are not encompassed therein and the only questions is whether it would be undue experimentation for one of ordinary skill in the art to determine the scope of the claim. This issue is discussed more fully below.

Thus, the only way that the issue of "undue experimentation" come up is if the PTO were to furnish reasons or evidence why the objective enablement of the present specification fails (none have been advanced) or it is alleged it would have been undue experimentation to determine the *scope* of the present method claims. This allegation has not been advanced, other than for the skin disorders" utility which is no longer at issue herein. Thus, the discussion of *In re Wands*, taking up a substantial amount of the Office Action, does *not* provide the necessary reasons or evidence as to why utility is deficient, but instead is reached only in other circumstances. However, since this analysis has been given considerable space in the Office Action, it will be addressed herein.

With respect to the nature of the invention, the *complexity* is in fact not supported by the breadth of the claim, as argued, for example, at page 3. In actuality, the nature of the invention is *not* complex, inasmuch as the use of 5-HT receptor binding compounds to treat various indications is well established and would be well understood by one of skill in the art, as discussed at page 2 of the specification.

With respect to the breadth of the claims, it is important to note that a determination of undue experimentation must be considered on a *compound by compound* basis. The mere fact that a claim is broad does *not* mean that it is undue experimentation is required to determine enablement of the compounds therein, if it is not undue experimentation to determine enablement for *each* compound in the scope of the claim. See, for example, *In re Colianni*, 195 U.S.P.Q. 150 (CCPA 1977). One of ordinary skill in the art can easily determine, with the protocols given in the specification, whether a given compound has the utility stated. Thus, the mere fact that many compounds must be tested is not dispositive of lack of utility.

With respect to the guidance given by the instant specification, is submitted that the guidance is adequate, inasmuch as pharmaceutical formulation information is given, one of ordinary skill in the art can clearly prepare the compounds for administration, dosages are given and the pharmaceutical art is well developed and administration of a compound for a given indication is quite routine. The discussion at pages 5 and 6 of the Office Action appears to be speculation on the part of the PTO that mechanisms are not well understood, however, elucidation of a mechanism is *not* necessary, where sufficient instruction is given to administer the compounds to produce the desired effect. Thus, it is submitted that this is also a non-issue.

With respect to working examples, it is well established that working examples are *not* required to provide enablement. See, for example, *In re Borkowski*, 164 U.S.P.Q. 642 (CCPA 1970).

With respect to the state of the art, PDE inhibitors are well known to be implicated in signaling pathways which are instrumental in the formation of tumors. Thus, it is again not seen that this is an issue. With respect to the quantity of invention necessary, this has been discussed above. It is maintained that the fact that a claim may be broad does not, in and of itself, result in undue experimentation, if the testing of, for example, each type of cancer or each autoimmune disorder is routine. Thus, this is not seen to be basis for lack of enablement.

In conclusion, it is submitted that the *Wands* factors clearly do not result in undue experimentation in order to determine whether a given cancer and/or autoimmune disease and/or a compound is within the scope of the present claims. Thus, objective enablement is clearly present, and withdrawal of the rejection under 35 U.S.C §112 is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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